

## PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

KING & WOOD PRC LAWYERS

Level 30, North Office Tower, Beijing Kerry Center,

1 Guanghua Road, Chaoyang District, Beijing 100020, China

PCT

WRITTEN OPINION OF THE INTERNATIONAL  
SEARCHING AUTHORITY

(PCT Rule 43 *bis*.1)

Date of mailing

(day/month/year)  
29 APR 2004 (29.04.2004)

Applicant's or agent's file reference

CIE042502PCT

REPLY DUE

within months/days from  
the above date of mailing

International application No.

PCT/CN2004/000134

International filing date (day/month/year)

20.FEB.2004(20.02.2004)

Priority date (day/month/year)

International Patent Classification (IPC) or both national classification and IPC

IPC7 G01N33/53, C12Q1/00

Applicant

BEIJING XINJING ANTAI MEDICAL AND TECHNOLOGY SERVICE LIMITED CORP., ETAL

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion  
☐ Box No. II Priority  
☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  
☐ Box No. IV Lack of unity of invention  
☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement  
☐ Box No. VI Certain documents cited  
☐ Box No. VII Certain defects in the international application  
☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/

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100088 Beijing, China

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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT / CN 2004 / 000134

**Box No. I      Basis of this opinion**

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing  
☐ table(s) related to the sequence listing

b. format of material

- ☐ in written format  
☐ in computer readable form

c. time of filing/furnishing

- ☐ contained in the international application as filed.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/CN2004/000134

**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

This questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,  
☒ claims Nos. 1-6,15

because:

- ☒ the said international application, or the said claims Nos. 1-6,15

relate to the following subject matter which does not require an international preliminary examination(*specify*):

Claims 1-6 relate to a method for diagnosing immunity recurrent spontaneous abortion, claim 15 relates to a method for monitoring therapeutics effect of immunity recurrent spontaneous abortion. All of the preceding claims relate to methods for the diagnosis or for the treatment of diseases, therefore not required to be searched by this Authority.

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_ are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported by the description that no meaningful opinion could be formed.

- ☐ no international search report has been established for said claims Nos. \_\_\_\_\_

- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

- ☐ has not been furnished  
☐ does not comply with the standard

the computer readable form

- ☐ has not been furnished  
☐ does not comply with the standard

- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

- ☐ See Supplemental Box for further details.

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/CN2004/000134

**Box No. V** Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

**1. Statement:**

Novelty (N)	Claims	7-14,16-18	Yes
	Claims		No
Inventive step (IS)	Claims	7-14,16-18	Yes
	Claims		No
Industrial applicability (IA)	Claims	7-14,16-18	Yes
	Claims		No

**2. Citations and explanations**

Claims 7-14,16-18 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not disclose or fairly suggest the invention drawn to the kits used for diagnosing immunity recurrent spontaneous abortion and monitoring therapeutics effect of immunity recurrent spontaneous abortion, and the claimed invention has clinical and commercial applications.